IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-95 (GMS)
CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	)	
Defendants.	)	

JOINT STATUS REPORT

Pursuant to Fed. R. Civ. P. 16, D. Del. L.R. 16.2, and the Court's July 5, 2018 Order Re: Case Management in Civil Cases (D.I. 37), the parties, by and through their undersigned counsel, jointly submit this Joint Status Report.

Counsel for the parties participated in a telephone conference pursuant to the Court's July 5, 2018 Order Re: Case Management in Civil Cases and as required by the Fed. R. Civ. 26(f). Specifically, on July 24, 2018, Jack B. Blumenfeld of Morris Nichols Arsht & Tunnell LLP and Robert J. Gunther, Jr., Andrew J. Danford, Nancy Lynn Schroeder, and Stephanie Lin of Wilmer Cutler Pickering Hale and Dorr LLP participated on behalf of Genentech, City of Hope, and Hoffmann-La Roche ("Plaintiffs" or "Genentech"). Robert V. Cerwinski, Cynthia Lambert Hardman, and Kevin J. DeJong of Goodwin Procter LLP participated on behalf of Celltrion, Inc., Celltrion Healthcare, Co., Ltd., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals International GmbH ("Defendants").

1. Jurisdiction and Service: Does the court have subject matter jurisdiction? Are all parties subject to the court's jurisdiction? Do any remain to be served?

The parties agree that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338. No party contests personal jurisdiction for the purposes of this action, and Defendants have waived service of the Summons and Complaint.

2. Substance of the Action: What are the factual and legal bases for plaintiffs' claims and defendants' defenses?

Plaintiffs' Position

This action concerns Defendants' efforts to make and market a trastuzumab product that is a proposed biosimilar to Genentech's cancer drug, Herceptin®. As set forth more fully in the Complaint, Genentech alleges that Celltrion's filing with the FDA of Biologics License Application No. 761091 seeking approval to market its proposed trastuzumab biosimilar ("Celltrion's Product") has infringed claims of forty U.S. Patents ("Asserted Patents"). Plaintiffs also allege that the manufacture, importation, offer for sale, sale, or use within the United States of Celltrion's Product would infringe those patents. As discussed below, Plaintiffs expect that they may be able to reduce the number of Asserted Patents to eighteen based upon the parties' contentions during the exchange of information under the Biologics Price Competition and Innovation Act ("BPCIA") and will be in a position to do so upon the resolution of their pending motion to dismiss Defendants' counterclaims and upon Celltrion's production of additional correspondence with the FDA, including the complete response letter that Celltrion received from the FDA earlier this year and related correspondence. Those eighteen patents are identified in paragraph 40 of the Complaint.

The Asserted Patents are identified in the following table by their numbers, expiry dates, and first named inventors.

Patent Number	Expiry	First Named Inventor
6,121,428	6/12/2018	Blank
6,242,177	6/05/2018	Simmons
6,331,415	12/18/2018	Cabilly
6,339,142	5/03/2019	Basey
6,407,213	6/18/2019	Carter
6,417,335	5/03/2019	Basey
6,489,447	5/03/2019	Basey
6,586,206	9/25/2020	Dixit
6,610,516	4/21/2020	Andersen
6,620,918	5/26/2019	Ansaldi
6,627,196	8/25/2020	Baughman
6,716,602	11/1/2021	Andersen
7,371,379	2/16/2022	Baughman
7,390,660	3/03/2023	Behrendt
7,449,184	1/05/2026	Allison
7,485,704	3/08/2025	Fahrner
7,501,122	1/01/2021	Adams
7,807,799	6/24/2024	Fahrner
7,846,441	5/06/2021	Hellmann
7,892,549	5/06/2021	Paton
7,923,221	12/18/2018	Cabilly
7,993,834	2/18/2022	Mass

Patent Number	Expiry	First Named Inventor
8,076,066	5/18/2021	Mass
8,357,301	4/24/2032	Belousov
8,425,908	12/10/2018	Hellmann
8,440,402	5/18/2021	Mass
8,460,895	8/08/2029	Eisenkraetzer
8,512,983	1/04/2031	Gawlitzek
8,574,869	7/08/2028	Kao
8,633,302	7/23/2030	Hepbildikler
8,691,232	2/21/2026	Derynck
8,771,988	11/20/2029	Goepfert
8,822,655	8/17/2031	Hepbildikler
9,047,438	5/06/2032	Belousov
9,080,183	8/23/2031	Klein
9,249,218	5/03/2019	Basey
9,428,548	1/14/2034	Brown
9,428,766	10/09/2028	Goepfert
9,487,809	1/14/2032	Zhou
9,714,293	8/06/2030	Gawlitzek

Defendants' Position

As set forth more fully in Defendants' Amended Answer, Affirmative Defenses, and Counterclaims to the Complaint, Defendants allege that the claims of the Asserted Patents are unpatentable under 35 U.S.C. § 101, are invalid under 35 U.S.C. §§ 102, 103 and/or 112, and/or

under the doctrine of obviousness-type double patenting, and that the manufacture, use, offer for sale, sale and/or importation into the United States of Celltrion's Product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of any asserted patent directly or indirectly by inducement or contributorily, literally or under the doctrine of equivalents, or in any other manner. (D.I. 38.)

Significantly, in their 42 U.S.C. § 262(l)(3)(C) statements, Plaintiffs provided no infringement contentions for 22 of the 40 asserted patents (highlighted in the chart above). In other words, they have implicitly conceded that Defendants' proposed trastuzumab product does not infringe those 22 patents. Contrary to Plaintiffs' assertions, there is no reason to link dismissal of these patents to a decision on Plaintiffs' motion to dismiss Defendants' counterclaims or to production of the Complete Response Letter, and Plaintiffs should promptly dismiss them.

3. Identification of Issues: What factual and legal issues are genuinely in dispute?

These are the principal factual and legal issues in dispute:

- the scope and construction of the claims of the Asserted Patents;
- whether Defendants have infringed and/or are infringing, directly or indirectly, any claim of the Asserted Patents, and if so, whether such infringement is willful;
- whether the claims of the Asserted Patents are invalid;
- whether Plaintiffs are entitled to equitable relief, including an injunction against Defendants' infringement of the Asserted Patents; and
- whether this case is "exceptional" under 35 U.S.C. § 285, and whether either side should be awarded its reasonable attorney fees, costs, and disbursements.

4. Narrowing of Issues: Can the issues in litigation be narrowed by agreement or by motions? Are there dispositive or partially dispositive issues appropriate for decision on motion?

a. Coordination with Other Herceptin® Biosimilar Cases

Plaintiffs' Position

This case is one of three patent infringement actions currently before the Court relating to proposed biosimilar versions of Genentech's Herceptin® drug. All the Herceptin® biosimilar cases are at an early stage, and Plaintiffs believe that it would be most efficient to place those cases on a coordinated schedule, which would allow common issues across those cases—including claim construction, inventor depositions, document discovery, discovery disputes, and expert discovery—to be addressed together.

There are currently two other patent infringement actions before the Court relating to proposed biosimilar versions of Genentech's Herceptin® drug involving developed by Pfizer (C.A. No. 17-1672-GMS) and Amgen (C.A. No. 18-924-GMS). The *Pfizer* case (which was filed less than two months before this case) is still at an early stage. Pfizer has answered the complaint; the most recent amended answer was filed on April 24, 2018. The parties in the *Pfizer* case have served initial discovery requests and are beginning document discovery. The *Amgen* case was filed on June 21, 2018, and Plaintiffs filed an amended complaint in that action on July 19, 2018, which Amgen answered on August 2, 2018.

In addition, Genentech anticipates soon filing a patent infringement action in this Court against Samsung Bioepis relating to its proposed Herceptin® biosimilar. Genentech and Samsung Bioepis are still exchanging information to determine the precise scope of that litigation, but Plaintiffs expect that they will bring that action against Samsung in the next one or two months. After the Samsung litigation is filed, Plaintiffs do not anticipate that there will be litigation involving any other proposed trastuzumab biosimilar products in the near term.

Because each of these cases involves proposed biosimilar versions of Genentech's Herceptin® drug, the issues across these cases overlap significantly. For example, the *Pfizer* and *Amgen* cases involve 16 of the 18 patents that Plaintiffs expect to remain in this case based upon the parties' BPCIA exchanges. These overlapping patents will present numerous common issues across these cases—such as claim construction, documentary and written discovery, inventor depositions, and expert discovery—that would be most efficiently addressed through a coordinated schedule. A coordinated case schedule will also allow the common issues in these cases to be addressed consistently, fairly, and efficiently—for example, by allowing the parties and the Court to address discovery disputes in a coordinated manner.

No schedule has yet been entered in the *Pfizer* or *Amgen* cases. The Court previously postponed holding a Rule 16 conference in the *Pfizer* case until this case was ready to be scheduled. *See* C.A. No. 17-1672-GMS, Mar. 26, 2018 Oral Order; C.A. No. 17-1672-GMS, D.I. 25, Apr. 9, 2018 Hr'g Tr. 11:22-12:12. Plaintiffs have proposed a schedule outlined below that would provide for a coordinated schedule that would allow for a bench trial in each of the Herceptin® biosimilar cases in April 2020. Plaintiffs believe that April 2020 is the earliest trial date that could be reasonably achieved while efficiently coordinating the overlapping issues across these multiple cases involving proposed Herceptin® biosimilar products.

However, these benefits of coordination cannot be obtained on a case schedule with a trial date in August 2019 as proposed by Defendants. For example, Defendants' proposed case schedule would have the parties begin the claim construction process in September 2018. Plaintiffs do not believe that beginning claim construction next month in this case is feasible, particularly since neither party has even served discovery. But beginning claim construction next month would also make coordination with the other trastuzumab biosimilar cases in the claim

construction process infeasible, if not impossible. Rather than proceeding with major case events with implications across these cases right away, Plaintiffs propose scheduling events such as claim construction so that the parties to ***all*** of the affected trastuzumab biosimilar cases may participate. Plaintiffs believe that this approach is far more efficient than Defendants' proposed schedule, which would guarantee that the Court and the parties to those other cases would need to repeat that work several months later in the other cases. Plaintiffs' proposed schedule, which builds in time to permit coordination, is also fairer to all involved because it will permit all interested parties to be heard at the same time on those overlapping issues.

Defendants contend that a trial date in August 2019 is feasible because Plaintiffs have had access to Defendants' aBLA FDA submission since August 2017 and have shared additional information as part of the patent dance. Defendants' proposed schedule also apparently relies on requiring Plaintiffs to narrow its patent infringement allegations to only eight patents and 20 claims in the next month. But this proposal ignores several key facts.

First, Celltrion announced on April 6, 2018 that it had received a complete response letter from the FDA, which has delayed the approval timeline for Celltrion's trastuzumab biosimilar product. Although Celltrion has apparently resubmitted its application to the FDA, Celltrion has yet to provide this resubmission to Plaintiffs. This resubmission will inform Plaintiffs' infringement allegations in this case, and the additional time provided under Plaintiffs' proposed schedule should allow the issues surrounding Celltrion's complete response letter and resubmission to crystallize before the parties undertake work that may need to be redone or ultimately prove unnecessary if the details of Celltrion's proposed biosimilar product and manufacturing process have changed as a result of this recent FDA correspondence.

Second, although this action was filed on January 12, 2018, it is in the same procedural posture as *Amgen*, filed six months later. Over the past six months, the parties have been working to address the issues raised by Celltrion's filing of a parallel declaratory judgment action in the Northern District of California. Defendants moved to dismiss or stay this case pending a resolution of the Northern District of California case. (*See* D.I. 12.) Celltrion's Northern District of California case was ultimately dismissed due to Celltrion's failure to complete the steps required under the BPCIA, and Defendants withdrew their motion to dismiss this case in June 2018. (*See* D.I. 28.) Defendants filed an amended answer and counterclaims on July 3, 2018. (*See* D.I. 36.) And there is a pending motion to dismiss and strike Defendants' counterclaims (D.I. 31), which will not be fully briefed until August 7, 2018. Amgen's August 2, 2018 answer was therefore filed less than one month after Defendants' answer in this action, and the parties have yet to serve discovery in either action. Defendants will not be prejudiced by an April 2020 trial date to allow coordination across the actions.

Third, an August 2019 trial date is not feasible and is inconsistent with the pace at which this case has been progressing due to Defendants' litigation strategy to date. Defendants initially refused to accept service of the Complaint through their outside counsel and eventually agreed to a waiver of service that gave them three months to respond to the Complaint. (*See* D.I. 11.) Defendants then filed a motion to dismiss or stay this case in favor of their own declaratory judgment action filed in the Northern District of California. (*See* D.I. 12.) Defendants withdrew that motion on May 29, 2018 after their Northern District of California case was dismissed as statutorily-barred because the Defendants failed to comply with the requirements of the BPCIA (*see* D.I. 28), and Defendants have appealed the dismissal of their California case to the Federal Circuit. Then, in an effort to cure their non-compliance with the BPCIA, Defendants attempted

to restart the patent dance and filed an amended answer and counterclaims on July 3, 2018. (*See* D.I. 36.) Having chosen to pursue a litigation strategy that has slowed the progress of this case over the last six months, Defendants cannot now demand that the case suddenly proceed to trial in just over a year. And in any event, it is not feasible that a case such as this—involving multiple asserted patents and a complicated technology—could be ready for trial on such a compressed schedule, particularly when considered in the context of the other trastuzumab biosimilar litigations that are ongoing in parallel. Indeed, even Pfizer—whose case was filed two months before this one—has not advocated a schedule that is as compressed as Defendants' proposed schedule here.

Defendants' Position

Defendants submit that the cases against all defendants can be trial ready within one year and therefore respectfully request a trial date in August 2019. Plaintiffs have had access to Defendants' aBLA FDA submission and confidential manufacturing information for nearly a year, since August 11, 2017, and the parties have already exchanged infringement and invalidity contentions on each of the asserted patents as part of the "patent dance."[1] Thus this case is already far ahead of where an ordinary pharmaceutical case would be at the close of pleadings. Indeed, as set forth *infra*, the parties agree to forego initial discovery under the Delaware Rules in this case in light of the exchange of contentions. The parties should not have any issue completing the remainder of pretrial activities within one year. Moreover, if, as Plaintiffs propose, trial were scheduled for April 2020 rather than August 2019, the later trial date could significantly delay cancer patients' access to Defendants' much needed, lower cost alternative to Herceptin.

[1] 42 U.S.C. § 262(l)(3)(B), (C)

Defendants do not object to coordinating the schedule in this case with Plaintiffs' other trastuzumab actions as long as this case is scheduled for trial in August 2019. It is Defendants' understanding that if the Court is inclined to enter Defendants' schedule, Pfizer would be willing to proceed accordingly. Plaintiffs, however, filed their case against Amgen more than six months after they filed the complaint in this action, and, if Plaintiffs file a case against Samsung Bioepis within two months as they say they will, that case will be eight months behind this action. To the extent the Amgen and potential Samsung Bioepsis cases cannot catch up in time to join Defendants' proposed schedule, Defendants respectfully request that they progress on a separate schedule in a second wave.

b. Celltrion's Product Launch

Plaintiffs' Position

Subject to the Court's approval, Plaintiffs have proposed a schedule with a trial date of April 2020. Plaintiffs believe that this trial date is only feasible if Celltrion does not launch its biosimilar product until after the entry of judgment following trial, which would simplify the issues in this case in several respects—for example, by avoiding separate proceedings regarding a preliminary injunction, eliminating the issue of damages for past infringement, and allowing Plaintiffs to narrow the patents asserted in this action to those with expiration dates after the trial date. In addition, because damages would not be at issue, this case could proceed with a bench trial and avoid the burden of pretrial summary judgment. If Celltrion launches its biosimilar product, the case schedule will need to be adjusted to allow for damages discovery and possible preliminary injunction proceedings. Indeed, although Celltrion asserts that damages could be addressed in a subsequent bifurcated trial if needed, Celltrion does not address the impact that a motion for preliminary injunction would have on the schedule. In addition, Plaintiffs believe that, if this became a damages case, that the damages issues would be intertwined with the issues of

infringement and validity, such that a single factfinder should address all of those issues together. Plaintiffs therefore believe that Defendants' suggestion to bifurcate damages is not efficient and potentially would violate Plaintiffs' Seventh Amendment right to have the same jury decide those issues.

Defendants' Position

The FDA is not projected to act on Defendants' aBLA until December 2018, and Defendants cannot launch their trastuzumab product until that time. Accordingly, Plaintiffs' discussion of adjusting the case schedule before it is even set is premature. Defendants submit that the case schedule should not be dependent upon whether or not Defendants decide to launch their proposed trastuzumab product at some point prior to trial. Even if Defendants were to ultimately launch their proposed trastuzumab product beforehand, trial on liability could proceed as scheduled. Depending upon the outcome of the trial on the merits, damages could then be addressed in a subsequent, bifurcated trial if needed. Moreover, Defendants submit that there is no basis to condition the trial date on Defendants refraining from launching their trastuzumab product – especially since delay could hinder patient access to a much-needed, lower-cost treatment.

c. Summary Judgment

Plaintiffs' Position

Assuming that Defendants agree not to launch a biosimilar product until after the entry of judgment following trial, Plaintiffs believe that including summary judgment in the schedule is not necessary, consistent with the Court's practice in bench trials. Contrary to Defendants' assertions, Plaintiffs are not "refusing" to drop patents; rather, there are several open issues (such as Celltrion's failure to provide Plaintiffs its most recent submission to the FDA and Plaintiffs'

pending motion to dismiss counterclaims) that may impact the scope of the patents at issue and the timing of such narrowing. (*See also* subsection (e) below.)

Defendants' Position

As set forth above, during the patent exchange pursuant to the BPCIA, Genentech did not provide a detailed statement of infringement for 22 of the 40 Asserted Patents; this is tantamount to an admission that Defendants' product does not infringe those patents.[2] While Plaintiffs state that they "expect to be able to" drop these patents, they have thus far refused to do so. To the extent Plaintiffs decline to dismiss these patents, Defendants respectfully request that the Court include deadlines for Summary Judgment in the schedule so that these patents are disposed of before trial. Moreover, Defendants do not agree to wait to launch their biosimilar product until after the entry of judgment following trial.

d. Default Standard for Discovery

Defendants propose that Plaintiffs produce the file history for each asserted patent by Friday, August 17, 2018.

Given the parties' exchanges of contentions under the BPCIA, the parties agree to forgo the initial discovery in patent litigation provided under Delaware Default Discovery Standard Rule 4 (b), (c), and (d).

The parties have proposed that any final supplementation of contentions occur by the close of fact discovery.

[2] Under 42 U.S.C. § 262(*l*)(B)(C), Genentech was to provide "a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing" of Celltrion's CT-P6 product.

e. Narrowing Asserted Patents

Plaintiffs' Position

Based upon the parties' exchanges of information under the BPCIA, Plaintiffs are prepared to narrow the number of asserted patents down to the eighteen patents identified in paragraph 40 of the Complaint. However, Plaintiffs have filed a motion to dismiss Defendants' counterclaims, which Plaintiffs believe are statutorily barred because Defendants failed to comply with the steps required under the BPCIA. (*See* D.I. 40.) Briefing on that motion is expected to be complete by August 7, 2018. Plaintiffs believe that a resolution of their motion to dismiss will determine the appropriate mechanism for narrowing the scope of the case—i.e., whether through a joint stipulation that addresses both Plaintiffs' claims and Defendants' counterclaims (if Defendants' counterclaims are not statutorily barred) or simply through an amended complaint (if Defendants' counterclaims are statutorily barred).

In addition, to the extent that Defendants do not launch their biosimilar product or engage in activity outside of the safe harbor provision in 35 U.S.C. § 271(e)(1), the number of asserted patents in this case will be reduced due to the expiration of certain asserted patents prior to trial.

Plaintiffs further disagree with Defendants' position that Plaintiffs should narrow the case to eight patents and 20 claims by August 31, 2018, so that claim construction can proceed starting in September 2018. Contrary to Defendants' assertions, this proposal ***is not*** consistent with this Court's recent order in Plaintiffs' case against Amgen's proposed biosimilar bevacizumab product. Rather, in the *Amgen* bevacizumab cases, such order was entered only ***after*** the parties had engaged in several months of discovery. *See Genentech, Inc. et al. v. Amgen Inc.*, C.A. No. 17-1407-GMS (D. Del.) (D.I. 66 (discovery requests served February 1, 2018), D.I. 70 (discovery requests served February 8, 2018), D.I. 106 (scheduling order entered May 18, 2018).) Defendants' proposal that Plaintiffs narrow the number of patents and claims in this case

by August 31, 2018 is untenable where neither party has served discovery, Plaintiffs still do not have Celltrion's resubmission to the FDA, and Defendants will not agree to delay a product launch until after trial (which would narrow the patents at issue in this action). Moreover, dismissing patents from a BPCIA litigation potentially has significant consequences for the remedies that Plaintiffs may seek. Plaintiffs believe that an order requiring Plaintiffs to unilaterally abandon their infringement claims for certain patents—without any commitment by the Defendants not to launch their product prior to the expiration of those patents—would be an unconstitutional taking of Plaintiffs' property rights and would violate principles of due process.

Defendants' Position

Defendants believe that this case should be narrowed in two steps.

First, Plaintiffs should provide Defendants with a covenant not to sue and a stipulation of dismissal for the 22 patents for which they have did not provide a detailed statement of infringement in their 42 U.S.C. § 262(*l*)(B)(C) BPCIA contentions. Plaintiffs have already stipulated to dismiss similar patents asserted in their cases against Pfizer and Amgen. *See Genentech, Inc. et al. v. Pfizer Inc.*, C.A. No. 17-01672-GMS (D. Del.) (D.I. 22); *Genentech, Inc. et al. v. Amgen, Inc.*, C.A. No. (D. Del.) (D.I. 16 & 17). Defendants proposed a similar stipulation in mid-June 2018, but Plaintiffs inexplicably rejected it. Defendants submit that dismissal of these 22 patents is unrelated to the merits of Plaintiffs' pending motion to dismiss, and that there is no reason for delay. Indeed, the only purported reason Plaintiffs give for delaying the dismissal of non-infringed patents from this case is that resolution of their motion to dismiss will determine the appropriate mechanism to do so.

Second, Plaintiffs should further narrow the case from 18 patents to 8 patents and 20 claims by August 31, 2018, two weeks prior to Defendants' proposed date for exchange of terms for claim construction. Defendants' proposed case schedule contemplates that Defendants will

update their production of Celltrion's aBLA to include all subsequent FDA submissions and correspondence, and that Plaintiffs will produce their BLA, by August 17, 2018. Defendants are amenable to this reciprocal document exchange as early as August 10, 2018. Defendants submit that these proposed deadlines therefore provide Plaintiffs with a reasonable opportunity to review this document production prior to narrowing their asserted patents and claims. These proposed deadlines would also provide the parties with certainty regarding the scope of the case prior to claim construction briefing and the exchange of expert reports.

Defendants' proposal for narrowing is consistent with this Court's recent order in Plaintiffs' case against Amgen's proposed biosimilar bevacizumab product. In that case, this Court ordered Plaintiffs to narrow the number of asserted patents from 26 to no more than 8 by August 31, 2018, and to narrow the number of asserted claims to no more than 20 by September 17, 2018. *See Genentech, Inc. et al. v. Amgen Inc.*, C.A. No. 17-1407-GMS (D. Del.) (D.I. 106); *Genentech, Inc. et al. v. Amgen Inc.*, C.A. No. 17-1471-GMS (D. Del.) (D.I. 104). Defendants believe that a similar schedule for narrowing the asserted patents and claims is appropriate here, given the significant number of patents that will remain even after the 22 concededly non-infringed patents are dismissed.

f. Second Complaint Against Celltrion

Plaintiffs' Position

As described in the Complaint, the parties initially engaged in the exchanges of information provided under the BPCIA. Before the parties could complete their exchanges under the BPCIA, Celltrion filed its own declaratory judgment action in the Northern District of California (Case No. 3:18-cv-274-WHO) on January 11, 2018. Plaintiffs filed the present action in the District of Delaware the next day, January 12, 2018.

Genentech filed a motion to dismiss the Northern District of California action on March 2, 2018 on the basis that any declaratory judgment claims by Celltrion were statutorily barred under the BPCIA because Celltrion had failed to complete the steps required under the BPCIA. The court in the Northern District of California granted Genentech's motion on May 9, 2018, finding that Celltrion had failed to comply with the steps required under the BPCIA and holding that Celltrion's declaratory judgment claims were thus statutorily barred under 42 U.S.C. § 262(*l*)(9). The court in the Northern District of California entered final judgment on June 11, 2018, and Celltrion has appealed that judgment to the U.S. Court of Appeals for the Federal Circuit (Nos. 2018-2160).

Celltrion initially moved to dismiss the present case in favor of its own declaratory judgment case filed in the Northern District of California. (*See* D.I. 12.) However, after the Northern District of California dismissed Celltrion's own declaratory judgment case as statutorily barred, Celltrion withdrew its motion to dismiss this case, answered the Complaint, and filed declaratory judgment counterclaims that mirror those dismissed in the Northern District of California case. (*See* D.I. 28, 29.)

Plaintiffs have moved to dismiss Celltrion's declaratory judgment counterclaims in this case on the same basis that the court in the Northern District of California held that those declaratory judgment claims were statutorily barred. (*See* D.I. 38.) In an effort to cure its non-compliance with the BPCIA, Defendants attempted to restart the patent dance in June 2018. Plaintiffs believe that Celltrion's attempt to restart the patent dance several months after abandoning it was legally impermissible and ineffective, but out of an abundance of caution, filed a second action against Defendants in this Court (Case No. 18-cv-1025) on July 11, 2018 in

order to preserve their rights in the event that Celltrion's attempt to restart the patent dance was legally permissible.

Plaintiffs, however, do not intend to pursue two separate cases against Celltrion and believe that their second-filed case should be consolidated with this case as a matter of efficiency. (*See* D.I. 39.) Plaintiffs believe that the second lawsuit should not be dismissed to avoid any suggestion that the dismissal of that lawsuit could trigger the patent holder's limitations on remedies under 35 U.S.C. § 271(e)(6). The parties are currently discussing the possibility of a stipulation to consolidate the second-filed case with this case.

Defendants' Position

As set forth in Defendants' Opposition (D.I. 45) to Plaintiffs' Motion to Dismiss, Defendants' counterclaims in this case are not statutorily barred. In any case, Plaintiffs' second-filed action against Defendants asserts the same 40 patents that are at issue in this action. Defendants believe that its counterclaims of non-infringement and invalidity will remain in either, or both, of the cases. Accordingly, in order to narrow the cases, Defendants proposed to Plaintiffs that they withdraw the pending motion to dismiss if the parties agree to consolidate the two cases. Plaintiffs have so far refused to withdraw their motion, and the parties are in further discussions regarding the possibility of a stipulation to consolidate the two cases.

5. Relief: What specific relief does plaintiff seek? What is the amount of damages sought and generally how is it computed?

Plaintiffs seek a judgment of infringement and willfulness; equitable relief, including a permanent injunction prohibiting Celltrion and anyone acting in concert with Celltrion from infringing the Asserted Patents; a determination that this is an exceptional case and an award of Plaintiffs' reasonable attorney fees, costs, and expenses; and such other relief as the Court may deem just and proper.

Defendants seek a judgment of noninfringement of any valid claim of any asserted patent; invalidity as set forth more fully in Celltrion's counterclaims; equitable relief, including enjoining the Plaintiffs and anyone acting with them from threatening or initiating litigation against Defendants or any present or prospective customers, dealers, or suppliers regarding any asserted patent; and a determination that this is an exceptional case and an award of Defendants' reasonable attorney fees, costs, and expenses; and such other relief as the Court may deem just and proper.

6. Amendments of Pleadings

Plaintiffs' Position

Plaintiffs intend to narrow the scope of the asserted patents to the eighteen patents identified in paragraph 40 of the Complaint based upon the information exchanged under the BPCIA. As discussed above, Plaintiffs believe that the Court's ruling on Plaintiffs' motion to dismiss Defendants' counterclaims will determine the appropriate procedural mechanism for narrowing the case. The parties have proposed a deadline in the case schedule for amended pleadings.

Defendants' Position

As set forth above, dismissal of the 22 patents for which Plaintiffs have identified no basis for infringement is a necessary first step to narrowing this case. Defendants respectfully submit that Plaintiffs should also amend their Complaint to further narrow the number of asserted patents to no more than 8 patents and 20 asserted claims.

7. Joinder of Parties

At this time, the parties do not intend to move to join any additional parties. However, as set forth in the parties' proposed case schedule, the parties have proposed that a deadline be set for joinder of parties.

8. Discovery: Discovery contemplated by each party and the amount of time it may take to complete discovery? Can discovery be limited? Are less costly and time consuming methods available to obtain necessary information?

The parties currently contemplate taking fact and expert discovery regarding the issues identified in Paragraph 3. The parties agree to negotiate in good faith to propose appropriate limits on discovery.

The parties' proposed case schedules are set forth below:

Event	**Genentech Proposed Deadline**[3]	**Celltrion Proposed Deadline**
Exchange Rule 26(a) Initial Disclosures	Tuesday, August 7, 2018	
Genentech to Produce File Histories for the Asserted Patents		Friday, August 17, 2018
Delaware Default Discovery Initial Disclosures (ID of custodians and data sources)	30 days after Rule 16 Conference	
Parties File Joint Proposed Protective Order	Friday, August 17, 2018	
Disclosure of Reliance on Advice of Counsel and, If Defendant Intends to Rely on Advice of Counsel, Production of Advice of Counsel Documents Complete	Monday, November 19, 2018	
Joinder of Other Parties or Amendment of Pleadings	Friday, January 4, 2019	Friday, August 31, 2018
Genentech to produce BLA No. 103792; Celltrion to produce any outstanding FDA amendments and correspondence regarding aBLA No. 761091		Friday, August 17, 2018

[3] Plaintiffs have shaded those boxes where Defendants have included events for which Plaintiffs do not agree should be part of the case schedule.

Event	**Genentech Proposed Deadline**[3]	**Celltrion Proposed Deadline**
Plaintiffs to identify no more than 8 asserted patents, and a maximum of 20 asserted claims		Friday, August 31, 2018
Exchange List of Terms to be Construed	Friday, February 8, 2019	Wednesday, September 12, 2018
Exchange List of Proposed Constructions	Friday, February 15, 2019	Wednesday, September 19, 2018
Meet and Confer to Narrow Claim Construction Disputes	Friday, February 22, 2019	Wednesday, September 26, 2018
File Final Joint Claim Construction Chart	Friday, March 1, 2019	Wednesday, October 3, 2018
Substantial Completion of Document Production	Friday, March 15, 2019	Friday, October 26, 2018
Simultaneous Opening Claim Construction Briefs	Friday, March 22, 2019	Wednesday, October 24, 2018
Simultaneous Answering Claim Construction Briefs	Friday, April 19, 2019	Wednesday, November 21, 2018
Claim Construction Hearing	May __, 2019	December ___, 2018
Final Contentions	Friday, August 16, 2019	Friday, February 15, 2019
Close of Fact Discovery	Friday, August 16, 2019	Friday, February 15, 2019
Opening Expert Reports on Issues on Which a Party Bears the Burden of Proof	Friday, September 20, 2019	Friday, March 15, 2019
Rebuttal Expert Reports	Friday, November 22, 2019	Friday, April 19, 2019
Close of Expert Discovery	Friday, January 17, 2020	Friday, May 31, 2019
Plaintiffs Draft Pretrial Order	Friday, February 7, 2020	Friday, June 28, 2019

Event	**Genentech Proposed Deadline**[3]	**Celltrion Proposed Deadline**
Joint Proposed Pretrial Order	Friday, February 28, 2020	Friday, July 26, 2019
Pretrial Conference	March __, 2020	Early to mid-August 2019
Bench Trial	April __, 2020	August 26, 2019

9. Protective Order:

In light of the expected production of confidential technical information in this case, the parties agree that a Protective Order and an order regarding the production of electronically stored information are needed. The parties will confer regarding the proposed orders and will submit them to the Court for approval. The parties will identify any areas of disagreement to the Court.

10. Estimated Trial Length: Is it feasible or desirable to bifurcate issues for trial? Is it possible to reduce the length of the trial by stipulations, use of summaries or statements, or other expedited means of presenting evidence?

Plaintiffs' Position

Given the overlapping issues with the other Herceptin® biosimilar cases, Plaintiffs believe that it may be efficient to consolidate some or all of the trial in this matter with the cases involving Pfizer, Amgen, and Samsung. Plaintiffs will discuss the format and length of a potentially consolidated trial with the defendants in the other Herceptin® biosimilar cases and provide the Court with a joint proposal.

As to Defendants' assertion that they will be prejudiced if this action is consolidated with the *Amgen* and *Samsung* actions, as described above, Defendants are in the same procedural position as Amgen where Amgen filed its answer only a month after Defendants filed their

answer in this action and where discovery has yet to take place in either action. A coordinated schedule across all actions is fairer to all involved because it will permit all interested parties to be heard at the same time on those overlapping issues.

Defendants' Position

Defendants agree that it may be efficient to coordinate some or all of the pre-trial activities in this case. With respect to the Pfizer action, coordination should pose no issue as that case was filed only two months before this litigation and is at nearly the same procedural posture. With respect to the case against Amgen and the potential case against Samsung, Defendants have no issue with coordination as long as those cases can proceed on Defendants' proposed schedule and be trial ready by August 2019.

With respect to the length of trial, Defendants respectfully submit that it is premature to estimate the length of the trial until after Plaintiffs narrow their case from the 40 Asserted Patents. If Plaintiffs narrow the case to 8 patents, Defendants expect that the trial could be completed within 8 days.

11. Jury Trial

Neither party currently seeks a jury trial. However, in the event that Defendants launch their biosimilar product prior to trial or engage in other allegedly infringing activity outside of the safe harbor provision in 35 U.S.C. § 271(e)(1), Plaintiffs believe a jury trial will be necessary, given that damages would be at issue.

12. Settlement: Have there been settlement discussions? What are the prospects for settlement? Is referral to the Magistrate for mediation or other ADR mechanism appropriate?

In-house counsel for the parties have had discussions regarding the possibility of settlement. The parties do not believe that referral to a magistrate or other ADR mechanism would be beneficial at this time.

13. Other Matters: Such other matters as counsel considers conducive to the just, speedy and inexpensive determination of this action.

Pursuant to Fed. R. Civ. P. 5(b)(2)(E), the parties have consented to electronic service, and have agreed that service of papers not filed with the Court may be accomplished by electronic mail addressed to all of the opposing party's counsel of record.

14. Statement Regarding Conference: A statement that counsel for the parties have conferred about each of the above matters.

Counsel for the parties have conferred about each of the above matters. Should the Court have any questions regarding the information set forth above, counsel will respond promptly.

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